UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION AT LAFAYETTE

RUBY ELI,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CAUSE NO. 4:20-CV-33-PPS-JEM
	)	
COLOPLAST CORP.,	)	
	)	
Defendant.	)	

OPINION AND ORDER

Ruby Eli had the defendant Coloplast Corp.'s pelvic mesh device (called a "sling") implanted to treat her urinary incontinence. After suffering from a variety of painful complications, Eli had a surgery to remove portions of the mesh device on January 16, 2018. She brought suit against Coloplast more than two years later, on May 21, 2020, for violations of the Indiana Product Liability Act ("IPLA").

Coloplast moves to dismiss under Rule 12(b)(6), arguing the claims are barred by the statute of limitations because Eli filed suit more than two years after the removal of her device, by which time surely she should have discovered the basis for this lawsuit. Indiana's discovery rule provides that the limitations period begins to run from the date the plaintiff knew or should have discovered the injury was caused by the product of another. Here, the amended complaint alleges "[i]t was not until recently that Plaintiff discovered the Altis Single Incision Sling System was defective and the cause of her pain, suffering, and complications." [Am. Compl., DE 19, at ¶ 52.] This allegation seems purposely vague, and I must admit to some degree of skepticism of it in light of

Eli's ongoing complications after the sling's implant, her decision to have removal surgery, and the widespread attention mesh devices have been getting for many, many years. However, at this early dismissal stage, where I must take the pleaded facts as true, there is a conceivable set of facts to support the conclusion that this lawsuit was timely filed. Therefore, Coloplast's motion to dismiss on this basis fails. However, the fraud claim is not pleaded with the sufficient degree of specificity, so I will grant the motion to dismiss on this claim only and allow Eli to re-plead that claim, if she chooses. The other arguments enumerated in Coloplast's motion do not warrant dismissal.

Background

The facts alleged in the amended complaint are straightforward. Coloplast develops, designs, manufactures and distributes medical devices for the treatment of female pelvic issues, primarily pelvic organ prolapse and stress urinary incontinence. [Am. Compl. ¶ 8.] Although most transvaginal meshes are comprised of non-absorbable synthetic polypropylene, Coloplast's Altis Single Incision Sling System is made of a synthetic, petroleum-based mesh. [*Id.* ¶ 11.] Eli alleges a number of specific defects with Coloplast's pelvic mesh products (including the sling), including that the mesh material harbors infections and migrates from the location of implantation. [*Id.* ¶ 19.] The complaint alleges that Coloplast under-reported and withheld information about the propensity of its pelvic mesh products to fail and cause injury or complications, and that it was aware of numerous defects in the mesh products. [*Id.* ¶¶ 24, 37.] Additionally, Eli contends there are safer feasible and practical alternatives. [*Id.*

¶ 31.]

Let's turn to Eli's personal experience with Coloplast's product. On June 17, 2016, Eli had surgery to treat her urinary incontinence. [*Id.* ¶ 48.] She had the Coloplast Altis Single Incision Sling System implanted. [*Id.*] Thereafter, Eli began experiencing severe and debilitating pain, painful intercourse (known as dyspareunia), incontinence and infections. [*Id.* ¶ 51.] As noted above, the amended complaint alleges "[i]t was not until recently that Plaintiff discovered the Altis Single Incision Sling System was defective and the cause of her pain, suffering, and complications." [*Id.* ¶ 52.]

Eli filed the complaint on May 21, 2020. [DE 1.] An amended complaint was filed on October 2, 2020. [DE 19.] It alleges one count for violations of the IPLA, with subclaims for defective manufacture and design, failure to warn, breach of express warranty, and fraud. Setting aside the fraud claim which Eli characterizes as a subclaim of the IPLA (which I will discuss later in this opinion), Eli's amended complaint is consistent with the IPLA because "[t]here are multiple theories on which a plaintiff can prove that a product was 'defective' under the IPLA: [a] product can be defective because of a manufacturing defect, a design defect, or a lack of adequate instructions and warnings." *Fisk v. Medtronic, Inc.*, No. 3:17-CV-032 JD, 2017 WL 4247983, at *4 (N.D. Ind. Sept. 25, 2017) (quotation omitted). Some courts in this district have used merger to combine separate counts for product liability torts into one statutory claim, while others have declined to do so. *See Hall v. Ehicon*, No. 3:20-CV-516-RLM-MGG, 2020 WL 6826489, at *2 (N.D. Ind. Nov. 20, 2020) (and cases cited therein). But I agree that

whether the claims are merged into a single claim or brought as separate claims under the IPLA is "largely a distinction without a difference" and is "entirely academic." *Id.* at *2-3 (quoting *Bailey v. Medtronic, Inc.*, No. 1:17-cv-02314-JMS-DML, 2017 WL 6035329, at *6 (S.D. Ind. Dec. 6, 2017)).

Discussion

I. Timeliness of the IPLA Claim in its Entirety

A plaintiff is not required to plead facts that overcome affirmative defenses based on the statute of limitations. *NewSpinSports, LLC v. Arrow Elecs., Inc.*, 910 F.3d 293, 299 (7th Cir. 2018). Thus, dismissing a complaint as untimely based on the pleadings is disfavored, because a statute of limitations defense largely turns on facts that aren't even before the court at this stage in the litigation. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., Inc.*, 782 F.3d 922, 928 (7th Cir. 2015); *see also United States v. Northern Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004) (dismissal under Rule 12(b)(6) on the basis of the statute of limitations is "irregular," since it is an affirmative defense for which the defendant bears the burden of proof).

Nevertheless, a plaintiff can plead herself out of court by alleging facts that make it plain that "relief is barred by the applicable statute of limitations . . ." *Logan v. Wilkins*, 644 F.3d 577, 582 (7th Cir. 2011). The Seventh Circuit has stated that a court may properly rule on an affirmative defense where the complaint "pleads too much and admits definitively that the applicable limitations period has expired." *Barry Aviation Inc. v. Land O'Lakes Municipal Airport Comm'n*, 377 F.3d 682, 688 (7th Cir. 2004).

However, "[a]s long as there is a conceivable set of facts, consistent with the complaint, that would defeat a statute-of-limitations defense, questions of timeliness are left for summary judgment (or ultimately trial), at which point the district court may determine compliance with the statute of limitations based on a more complete factual record." *Sidney Hillman*, 782 F.3d at 928.

Under the *Erie* doctrine, a federal court sitting in diversity applies the substantive law of the state in which it sits. *See Land v. Yamaha Motor Corp.*, 272 F.3d 514, 516 (7th Cir. 2001). Statutes of limitations fall firmly on the substantive side of the *Erie* substance/procedure divide. *Guaranty Trust Co. v. York*, 326 U.S. 99, 110 (1945); *see also Hollander v. Brown*, 457 F.3d 688, 694 (7th Cir. 2006) (same). Here, the parties agree that the applicable statute of limitations arises under the IPLA which provides that "a product liability action must be commenced: (1) within two (2) years after the cause of action accrues; or (2) within ten (10) years after the delivery of the product to the initial user or consumer." Ind. Code § 34-20-3-1(b). The Indiana Supreme Court has interpreted this statutory language to require IPLA claims to be filed *both* within two years after the cause of action accrues and within ten years after the delivery of the product to the initial user or consumer. *Estabrook v. Mazak Corp.*, 140 N.E.3d 830, 835 (Ind. 2020) (specifically finding that the legislature wrote "or" but meant "and."). Here, the timeliness dispute centers around whether Eli filed within two years after her cause of action accrued.

Indiana has adopted the discovery rule for the accrual of claims arising out of

tort. *See Wehling v. Citizens Nat'l Bank*, 586 N.E.2d 840, 842-43 (Ind. 1992). In Indiana, the statute of limitations has two prongs: "the Indiana statute of limitations begins to run from the date that the plaintiff knew or should have discovered (1) that the plaintiff suffered an injury or impingement and (2) that the injury or impingement was caused by the product or act of another." *Evenson v. Osmose Wood Preserving Co. of Am., Inc.*, 899 F.2d 701, 703 (7th Cir. 1990); *see also Wehling*, 586 N.E.2d at 843. In other words, the statute of limitations in this case commences on the date Eli knew or should have discovered that she suffered an injury, and that the injury was caused by Coloplast's sling. *See Barnes v. A.H Robins Co., Inc.*, 476 N.E.2d 84, 86 (Ind. 1985).

When an action accrues is often a question of fact. *Evenson*, 899 F.2d at 705. The pertinent question is whether the plaintiff "experienced symptoms that would cause a person of reasonable diligence to take action that would lead to the discovery of [her] cause of action." *Hall*, 2020 WL 6826489, at *5 (quoting *DuRocher v. Riddell, Inc.*, 97 F. Supp. 3d 1006, 1029 (S.D. Ind. 2015)). "Once a plaintiff's doctor expressly informs the plaintiff that there is a reasonable possibility, if not a probability, that an injury was caused by an act or product, then the statute of limitations begins to run and the issue may become a matter of law." *Id.* (quoting *Degussa Corp. v. Mullens*, 744 N.E.2d 407, 411 (Ind. 2001)). But "a plaintiff's mere suspicion or speculation that the product caused the injuries is insufficient to trigger the statute." *Id.*

In this case, we can't tell from the amended complaint when Eli knew or should have known that she suffered an injury caused by Coloplast's sling. We don't know

exactly what symptoms she was suffering from and when, what her physicians told her about any complications from the implant, what Eli believed was at the root of her pain and symptoms, what the doctors found during the removal procedure (for example, was the mesh eroded?), and we don't know what Eli was told post-removal surgery. Discovery may very well show that Eli became aware of or was actually told at a certain time that her injuries were caused by a defective mesh (and were not just the result of a common side effect or something else), and that date might very well prove that the statute of limitations had lapsed by the time she filed suit. But we have no way of knowing the answers to any of these questions at this point in time.

On a motion to dismiss, I can only look at the face of the complaint to determine if the statute of limitations has run. Because the amended complaint alleges it wasn't until "recently" that Eli discovered the sling was defective and caused her injuries, and there are no other allegations to the contrary, that is sufficient to survive a motion to dismiss. [Am. Compl. ¶ 52.]

Coloplast's point that Eli must have known by the time of her removal operation that the sling was causing her injuries is well taken. That certainly seems intuitive, but cases have to be decided on evidence and not intuition. It is telling, therefore, that the cases cited by Coloplast were all decided on summary judgment. *See Dahms v. Coloplast Corp.*, No. 19 C 63649, 2020 WL 5593279, at *3 (N.D. Ill. Sept. 18, 2020); *Stark v. Johnson & Johnson*, No. 18 cv 06609, 2020 WL 1914767, at **2, 4 (N.D. Ill. Apr. 20, 2020); *Curtis v. Mentor Worldwide, LLC*, 543 F. App'x 901, 904 (11th Cir. 2013). Those cases actually

bolster my belief that dismissal is not appropriate in this instance on a motion to dismiss, and the timeliness of this action is best suited for review on summary judgment (or at trial) instead. *See, e.g., Karnes v. C.R. Bard, Inc.*, 18-cv-931-wmc, 2019 WL 1639807, at *4 (W.D. Wis. Apr. 16, 2019) (denying motion to dismiss similar mesh case, rejecting the argument that plaintiff must have known at the latest by the removal surgery that the mesh must have caused her injuries, and finding "additional factual development is required to determine precisely *when* plaintiff had an objective basis for assessing [defendant's] role in causing her injuries.").

Because I find dismissal on the basis of the two-year statute of limitations is inappropriate (at least at this point), I need not address Eli's secondary claim that the statute of limitations should be tolled due to fraudulent concealment. [Am. Compl. ¶¶ 56-57.] The same goes for Eli's argument that the warranty claims are actually governed by the four-year limitations period outlined in Indiana Code § 26-1-2-725. I need not decide this issue right now because I have found dismissal of the single (and all-encompassing) IPLA claim under the two-year statute of limitations is not presently appropriate. So whether the true statute of limitations for the breach of warranty subclaim is really two years or four years is irrelevant at this point.

II. Sufficiency of the Failure to Warn Subclaim

In addition to the timeliness of Eli's amended complaint, Coloplast also attacks the sufficiency of several subclaims. First, Coloplast argues that Eli has failed to state a subclaim for failure to warn because: (1) Coloplast's legal duty was merely to warn Eli's

physician (and not her) of risks not already known to them; and (2) the amended complaint fails to plead that her physician relied on Coloplast's warnings in making their treatment decisions. [DE 25 at 7-10.]

Even assuming that Coloplast's only obligation was to warn her physician, recovery under the factual allegations in the amended complaint is still possible. Under the learned intermediary doctrine, "a manufacturer has no duty to warn the ultimate user when it sells the product to a knowledgeable or sophisticated intermediary." *Hathaway v. Cintas Corporate Servs., Inc.*, 903 F.Supp.2d 669, 676 (N.D. Ind. 2012). Coloplast tries to fault Eli's complaint because she alleges in several places that she personally was not instructed or warned of the risks posed by the sling. [Am. Compl. ¶¶ 78-92.] However, the amended complaint *also* alleges that Coloplast failed to warn her implanting physician of the risks and dangers of the device. [*Id.*] Specifically, she alleges that "Coloplast failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians, including Plaintiff's implanting physician," and then lists six risks and dangers of the device about which Coloplast failed to warn. [*Id.* ¶ 83.] The allegations in the complaint don't run afoul of the learned intermediary rule, as Eli has alleged that Coloplast failed to warn *both* herself and her physician. *See, e.g., Tague v. Wright Med. Tech., Inc.*, No. 4:12-CV-13-TLS, 2012 WL 1655760 (N.D. Ind. May 10, 2012) (denying motion to dismiss in defective prosthetic hip device case, finding where Plaintiff alleged that no warnings at all were provided, a learned intermediary was included in the people who did not

receive a warning).

To the extent Coloplast argues the amended complaint does not include allegations that the implanting physician was unaware of the risks (and that Coloplast failed to warn her healthcare providers of risks not already known to them), I think this fails to take into consideration the complaint as a whole. Eli has made multiple allegations that Coloplast concealed and misrepresented specific risks and dangers associated with the mesh device. [Am. Compl. ¶¶ 57, 100, 113, 123, 126, 129, 130, 148, 150.] This should suffice. After all, a plaintiff is not required to plead legal theories, *Hatmaker v. Mem'l Med. Ctr.*, 619 F.3d 741, 743 (7th Cir. 2010), and the detailed amended complaint certainly puts Coloplast on notice of the claims against it.

Coloplast also argues that the failure to warn claim fails for another reason, which is Eli has not pleaded any factual allegations to demonstrate that her medical providers actually relied on the substandard warnings. [DE 25 at 9.] Yet Eli alleges that her "implanting physician relied on Coloplast's aforementioned representations, warnings, instructions, and marketing materials" that did not include the enumerated risks and complications alleged in the complaint when the physician recommended the implantation of the sling inside Eli. [*Id.* ¶ 79.] This is adequate. Whether a different warning could have led to a different outcome in this case (for example, Eli's physicians would not have implanted the sling had they received different warnings), is a question of fact that must be decided later in this case.

III. Sufficiency of the Breach of Warranty Subclaim

Coloplast argues that Eli failed to set forth a sufficient claim for breach of warranty because she did not provide adequate notice to Coloplast of the defect. [DE 25 at 10-11.] It is well established that in breach of implied warranty of merchantability cases, one necessary precondition is the seller must be given notice of the product defect prior to the plaintiff filing suit. *See, e.g., Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, No. 4:05 CV 49, 2006 WL 299064, at *4 (N.D. Ind. Feb. 7, 2006).

Eli alleges that she gave notice of the breach of implied warranty to Coloplast in a demand letter dated May 1, 2020. [Am. Compl. ¶ 114.] Coloplast contends this notice is untimely - clinging to its argument that the case should have been filed at the latest two years after the removal surgery, or by January 16, 2020, so this notice is too late. As explained earlier in this opinion, when Eli's claim accrued is still a question of fact that needs to be fleshed out during discovery. If it is ultimately determined that the case was timely filed on May 21, 2020, then giving notice on May 1, 2020 seems to be appropriate.

Coloplast also attacks the breach of warranty claim by arguing that Eli did not plead specific facts that the mesh was not merchantable or fit for its intended purpose. [DE 25 at 11.] To the contrary - Eli has set forth the necessary facts. She alleges that the mesh device's purpose was to treat urinary incontinence and she had it implanted for this purpose. [Am. Compl. ¶¶ 117, 48.] She also alleges that after the implant, she continued to suffer incontinence and developed other complications including pain and

infections. [*Id.* ¶ 51.] Eli then specifically states: "[t]he Altis Single Incision Sling System was not merchantable or fit for its ordinary purpose at the time of manufacture and conveyance to the Plaintiff; that purpose being to treat Plaintiff's urinary incontinence." [*Id.* ¶ 117.] Taking all the facts pleaded as true, and drawing all reasonable inferences in Eli's favor, as the law requires on a motion to dismiss, the amended complaint sets forth an ample claim for breach of warranty.

IV. Sufficiency of the Fraud Subclaim

Coloplast asserts that Eli's "subclaim" for fraud [Am. Compl. ¶¶ 120-54] fails because she has not stated with particularity the circumstances constituting fraud. [DE 25 at 11-12.] As I alluded to at the beginning of this opinion, a claim for fraud might not even be properly brought under the IPLA because under that statute, "[a] product can be defective because of a manufacturing defect, a design defect, or a lack of adequate instructions and warning." *Fisk*, 2017 WL 4247983, at *4. But it's neither here nor there. Regardless of whether the allegations of fraud belong under the IPLA or should really be pled as a separate count, the parties agree that Rule 9(b) imposes a heightened standard for pleading fraud in this case. Fed. R. Civ. P. 9(b). And here, Eli has not satisfied that heightened standard.

To fulfill the particularity requirement imposed by Rule 9(b), Eli must plead "the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the Plaintiff." *Cornielsen v. Infinium Capital Mgmt., LLC*, 916 F.3d 589,

599 (7th Cir. 2019) (internal citations omitted). Here, Eli has not sufficiently alleged the who, what, where, when, and how of her fraud claim.

Eli alleges that Coloplast generally is the identified tortfeasor. Regarding how the alleged misstatements were made and where, the amended complaint states:

> The information distributed to the public, the medical and healthcare community, the FDA, and Plaintiff and her implanting physician, by Coloplast included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Coloplast Pelvic Mesh Products.

[Am. Compl. ¶ 133.] While this alleges that Coloplast misrepresented that its mesh products in general were safe, Eli does not allege the specific "how" and "where" as to the misrepresentations about the Altis Single Incision Sling System. For example, which websites did Coloplast use? What professional meetings contained false statements? Which particular Coloplast sales people made the alleged false statements? And most importantly, what in particular was said about the sling that was false? Additionally, while Eli lists the date of her implant surgery as June 17, 2016, she gives no additional specifics about the timing of the misrepresentations.

Eli has not "show[ed], in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy." *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854-55 (7th Cir. 2009).

There is just not enough specifics for the fraud claim to survive a motion to dismiss.

Consequently, I will grant the motion to dismiss as to the subclaim for fraud. However, I do recognize that the Seventh Circuit has instructed when a plaintiff's complaint is dismissed under Rule 12(b)(6), the general rule is to give at least one opportunity to amend the complaint before the action is dismissed. *Runnion ex rel. Runnion v. Girl Scouts of Greater Chicago & Nw. Indiana*, 786 F.3d 510, 519 (7th Cir. 2015). While I have substantial doubts that this IPLA case is really about fraud, the dismissal will be without prejudice. Eli is granted leave to re-file only the fraud subclaim, if she chooses, and cure the pleading deficiencies, if she can, as discussed in this opinion.

Conclusion

In sum, Coloplast might very well have a viable statute of limitations defense. But its efforts to dismiss Eli's claim on that ground at this point in the litigation are premature. For the reasons set forth above, Coloplast's motion to dismiss the first amended complaint [DE 24] is **GRANTED IN PART AND DENIED IN PART**.

The motion is DENIED as to all claims under the IPLA other than fraud, and these claims remain pending. The motion is GRANTED as to the fraud subclaim which is DISMISSED WITHOUT PREJUDICE. Eli is granted leave to re-file and cure the pleading deficiencies within 30 days from the date of this Order. Should Eli file a second amended complaint, the deadline for Coloplast to answer or otherwise respond to Eli's complaint will be within 14 days after service of the amended pleading consistent with Fed. R. Civ. P. 15(a)(3). Should Eli choose not to file a second amended

complaint, the deadline for Coloplast to respond to Eli's amended complaint shall be February 22, 2021.

SO ORDERED.

ENTERED: January 7, 2021.

/s/ Philip P. Simon
PHILIP P. SIMON, JUDGE
UNITED STATES DISTRICT COURT